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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------------|
| 10/595,027 | 09/01/2006 | Anthony Lambert | BRYE0102PUSA | 1465 |
| 22045 7590 11/10/2008 BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075 | | | EXAMINER EASTWOOD, DAVID C | |
| | | | ART UNIT 4185 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------------|--|
| Office Action Summary | Application No. 10/595,027 | Applicant(s) LAMBERT, ANTHONY | |
| | Examiner DAVID EASTWOOD | Art Unit 4185 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/72006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Drawings

1. The drawings are objected to because Figure 3 does not represent the integral orchidopexy surgical tunneler and is not representative of this instant application. Figure 3 is representative of a device with removable heads and is not representative of this instant application. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Richmond (US 4509516).

Regarding Claim 1, Richmond discloses an elongated body (Column 5 line 66) having a tunneling head with a testical attachment means by surgical stitch or eyelet (Column 6 line7) at the end opposite the tunneling head. (Figure 1 item 13), (Figure 5 item 13)

Regarding Claim 2, Richmond discloses an attachment means comprising an aperture in the end of the body opposite the tunneller head (Column 6 line7), (Figure 1 item 13), (Figure 5 item 13)

Regarding Claim 3, Richmond discloses an arcuate elongated body (Column 5 line 66-67)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 4185

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determining the scope and contents of the prior art.
Ascertaining the differences between the prior art and the claims at issue.
Resolving the level of ordinary skill in the pertinent art.
Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 4, 6-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond in view of medical toys.com (Here after referred to as Rosebud Sounds).

Regarding Claim 4, Richmond discloses the claimed invention except for *the tunneller head is of a shape and size representative of a human testis*.

However, Rosebud Sounds (Urethral dilator) discloses the tunneller head with a shape and size representative of a human testis (Figure 3)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Richmond's invention with the tunneller head having a shape and size representative of a human testis in order to clear a pathway for the undescended testicle to travel to the scrotal pouch.

Regarding Claims 6, Richmond discloses the claimed device except for *a size range representative of the size and shape of the human testis*.

However, Rosebud sounds discloses a size range representative of the size and shape of the human testis. (figure 2 Rosebud sounds) This size range is represented by individual integral Rosebud sounds contained in a kit where each sound represents a different sized head (Rosebud sounds fig.2) .

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Richmond with the size range representative of the size and shape of the human testis in order match the correct testi size of a diverse group of patients with varying testi sizes to clear a pathway for the undescended testicle to travel to the scrotal pouch.

Regarding Claim 7, Richmond discloses the claimed invention except for the individual sounds in the kit are integral and one piece.

However, Rosebud sounds discloses the individual sounds in the kit are integral and one piece. (figure 1,2,3 and 4)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Richmond with the individual sounds in the kit being integral and one piece as taught by Rosebud sounds in order to simplify the surgical process by having a plurality of sizes to choose from in order to better match the patients anatomical parameters.

Regarding Claim 8, Richmond's invention as modified by Rosebud sounds disclose the claimed invention except for the tunneller in unidirectional.

It would have been obvious to one of ordinary skill in the art at the time of invention that the device would be unidirectional in nature when applied to an orchidopexic application.

Regarding Claim 9, The invention of Richmond, as modified by Rosebud sounds disclose the claimed invention except for a method of orchidopexy surgery.

It would have been obvious that the disclosed device would need to be inserted through an incision made in the abdominal wall.

It would have been obvious to have the undescended testicle attached by means of stitch to the eyelet end opposite that of the tunneling end in order to complete the orchidopexic procedure.

It is obvious that the nature of the design of the device would dictate a unidirectional feeding of the device from the incision in the abdominal wall through to the scrotal sac, forming a pocket for the testicle to reside.

It would have also been obvious that an incision at the scrotal sac would be made to retrieve the device and lead the attached descended testical to the newly formed scrotal pocket.

It would have been obvious to then detach the device from the newly descended testicle and close all incisions made during the procedure.

Regarding Claim 10, Richmond's invention as modified by Rosebud sounds discloses the claimed invention except for a method for attaching the testicle. However, It would have been obvious to stitch the testical to the eyelet end of the tunneller as disclosed by Richmond (Column 6 line7)

Regarding Claim 11, The invention of Richmond, as modified by Rosebud sounds disclose the claimed invention except for *the testis is attached to the tunneller towards an end thereof remote from the said tunneller head.*

It would have been obvious to attach the testicle to the opposite remote end of the tunneller in order to facilitate the testicle to follow the tunneller through the path toward the scrotal sac which had been created by the tunneling head.

Regarding claim 12, The invention of Richmond, as modified by Rosebud sounds disclose the claimed invention except for *selecting a subcutaneous tunneller from a set of subcutaneous tunnellers having different size tunnelling heads, the selected tunneller having a tunnelling head which corresponds in size with the size of the said testis to be repositioned.*

It would have been obvious to select a tunneller from a plurality of tunnellers in a kit in order to match the testicle size of the patient so that undo harm and stress is not applied to the tissue either by selecting a tunneller too large and damaging the surrounding tissue during the procedure or selecting a tunneller too small and damaging the testicle during the procedure.

Regarding Claim 13, The invention of Richmond, as modified by Rosebud sounds discloses the claimed invention except *the tunneller is fed through the said incision in the said scrotum to remove the tunneller from the body.*

It would have been obvious that an incision at the scrotal sac would be made to retrieve the device. Detaching the device from the newly descended testicle and closing all incisions made during the procedure.

7. Claims 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond in view of medical toys.com (Here after referred to as Rosebud Sounds) in view of Tal (US 2003/0088212).

Art Unit: 4185

Regarding Claim 5, Richmond's invention as modified by Rosebud sounds disclose the claimed device except for the device can be made of a titanium alloy.

However, Tal discloses a tunneler which is made of a titanium alloy. (column 3 paragraph 23).

It would have been obvious to one of ordinary skill in the art at the time of invention that the device disclosed by Richmond and Rosebud sounds can be fabricated out of a titanium alloy. The use of Titanium alloys for this class of device is well known to one of ordinary skill in the art at the time of invention.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Erwin Hans Hubrich; Thoma (GB 1546172 A), Paul Friedrich Francke (US 343306), Arthur J. Beavis (US 507060), W.D.Kearns (US 672377), Adler, Barry G. (US 3747603), Sandler, Jack (US D247512), Machek, James E. (US4895168), Waldvogel, Chester W. (US 5061245), Resnick et al. (US 5651790), Ulmsten, Ulf (US 6491703), Navis, John A. (US 6589212), Feeley et al (US 2007/0078396), Burbank et al (US 7229439), Hacklaender, Andreas Dr. (DE 4334419), Lambert, Anthony (GB 2392623).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is

Art Unit: 4185

(571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)2724797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 4185

/Terrell L McKinnon/

Supervisory Patent Examiner, Art Unit 4185